

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Jonnie R. WILLIAMS)
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Serial No.: 09/668,144) Group Art Unit: 1731
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Filed: September 25, 2000) Examiner: Colaianni, M.
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For: IMPROVED METHOD OF TREATING) Atty. Dkt. No.: 04859.00006
TOBACCO TO REDUCE NITROSAMINE)
CONTENT, AND PRODUCTS PRODUCED)
THEREBY)

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**INFORMATION DISCLOSURE STATEMENT, INCLUDING DISCUSSION
OF REFERENCES IN SUPPORT OF PETITION TO MAKE SPECIAL**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The patents and documents listed on the attached PTO-1449 (six sheets) are deemed most closely related to the subject matter encompassed by the claims of the present application. Copies of the documents are available to the Examiner in Application Serial No. 09/397,018 and/or 08/998,043, the benefit of which is claimed by the subject application under 35 U.S.C. § 120, and are not being submitted at this time pursuant to 37 C.F.R. § 1.98(d). This Information Disclosure Statement is being filed to support the accompanying Petition to Make Special Under 37 C.F.R. §1.102(d). The patents and documents were found in pre-examination searches and/or were cited in related applications.

The subject matter of the subject application relates to a process of substantially preventing the formation of at least one nitrosamine in tobacco during the curing.

RELEVANCE OF THE REFERENCES

The following references are relevant for their respective disclosures discussed below:

Andersen et al., Accumulation of 4-(N-Methyl-N-nitrosamino)-1-(3-pyridyl)-1-butanone in Alkaloid Genotypes of Burley Tobacco during Postharvest Processing: Comparisons with N'-Nitrosornicotine and Probable Nitrosamine Precursors, Cancer Research Vol. 45, Nov. 1985, pp. 5287-5293. ("Anderson '85")

Anderson '85 describes the relationship of NNK, NNN, and their "probable precursors," i.e., nitrate, nitrite, and alkaloids, as determined (a) after the growth of Ky 14 burley tobacco under different shade conditions followed by air curing; and (b) during preparation of air-cured and homogenized-leaf-cured (HLC) burley tobaccos from conventionally-grown tobaccos of different alkaloid type. Anderson '85 reported *inter alia* that air-cured Ky 14 burley tobacco (middle leaf position on stalk) grown in 65% shade had an NNK content of 0.18 µg/g and an NNN content of 1.5 µg/g (Table 2, p. 5289). Air-cured and HLC tobaccos of different alkaloid types, when dried, were found to contain higher NNN and NNK levels (Table 1, p. 5289 and Table 4, p. 5291).

W.J. Chamberlain et al., Effects of Curing and Fertilization on Nitrosamine Formation in Bright and Burley Tobacco, Phytochemical Research Unit, USDA, Agricultural Research Service, Beitrage zur Tabakforschung International, Vol. 15, No. 2, April 1992 ("Chamberlain '92")

Chamberlain '92 describes the effects of nitrogen fertilization on alkaloid and nitrosamine levels in lamina of air-cured and flue-cured tobacco. At page 89, Table 1, Chamberlain '92 reports that air-cured KY 14 and G 28 tobacco which was grown in the absence of nitrogen fertilization had NNN contents of about 0.12 and 0.04 µg/g, respectively, and total TSNA contents of about 4.28 and 1.86 µg/g, respectively.

W.J. Chamberlain et al., Studies on the Reduction of Nitrosamines in Tobacco, Tobacco International, (1986) Vol. 188, No. 16, pp. 38-39 ("Chamberlain '86")

Chamberlain '86 reported a 76% reduction in the amount of NNN in flue-cured NC 2326 leaves by spraying ascorbic acid on harvested leaves (bottom of p. 38). Chamberlain '86 concluded that ascorbic acid had no effect in reducing NNN when sprayed on leaves that were still on the plant (p. 39 bottom of col. 1).

Marley U.S. Patent 4,790,335

Marley describes an apparatus for curing tobacco which employs a gas tank (typically propane) for fueling dual heating systems which heat separate chambers (52, 54) for curing the leaves and stems, respectively. Combustion exhaust gases produced by burning the gas fuel source in heater blowers (40 and 42) are circulated through the open conveyor chambers during curing of the tobacco to somehow provide zones with controlled temperatures.

The description in the specification along with the apparatus shown in the drawings depict direct-fired heating. There is no provision for exhausting combustion gases except through the lines leading to the heating chambers. Marley does not describe avoiding an anaerobic condition around the vicinity of the tobacco leaves during curing, and does not describe or suggest a controlled environment capable of substantially preventing the formation of at least one nitrosamine.

Beckett et al. U.S. Patent 5,431,175

Beckett describes providing proportional-integral-derivative (PID) control for controlling humidity or wet bulb temperature within a drying structure during curing and drying of tobacco or other agricultural products. A controller continuously controls the quantity or amount of air exhausted from the drying structure and the amount of air induced or brought into the drying structure, so as to compensate for dynamic changes within the material being cured and for outside environmental changes (column 2, lines 48-65). Beckett does not describe avoiding anaerobic conditions nor does the document address nitrosamine formation in tobacco.

Crump, III et al. U.S. Patent 5,335,590

Crump '590 discloses an apparatus for reordering or drying tobacco. The device has a plurality of chambers which are said to increase vertical flow through a packed bed of a conveyed product. The device also is said to avoid excessive mechanical resistance to rotation of the spiraling conveyor stack from an abundance of seal strips, to channel the air through the

conveyor stack (column 5, lines 9-14). Crump '590 does not describe avoiding anaerobic conditions nor does the document address nitrosamine formation in tobacco.

Joubert et al. U.S. Patent 4,470,422

Joubert discloses a method and apparatus (barn) for curing tobacco employing circulating air to dry tobacco leaf. The apparatus includes temperature control means for maintaining a predetermined temperature or humidity difference between upper and lower zones inside the barn, which is said to avoid shock effects to the leaf (column 1, lines 59-64). The curing process is said to depend on the state of the leaf and on conditions inside the barn, while not being influenced by ambient conditions (column 2, lines 1-6). Joubert does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Mitchell et al. U.S. Patent 4,212,634

Mitchell discloses a tobacco barn having a conventional forced air heating system including a fan and a gas ring burner (column 3, lines 61-66). The barn also has an auxiliary heating system which can be a wood or coal burning stove (column 2, lines 29-32). A temperature controller controls both heating systems to maintain a desired temperature within the barn during curing and drying (column 4, lines 33-64). The heated air generated by the conventional forced air system is directed by the fan into a heat exchanger of the auxiliary heating system and thereafter returned to the barn (column 5, lines 20-63). Mitchell does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Touton U.S. Patent 3,024,792

Touton '792 describes a tobacco curing apparatus in which the amount of air circulated is regulated in accordance with the total evaporation from the tobacco and is established so as to minimize reductions in tobacco temperature due to evaporative cooling (column 2, lines 45-50). After passing through the tobacco bed, the air is treated by a conditioning unit and recirculated.

A portion of the damp air is replaced with fresh air to maintain the desired rate of evaporation (column 2, lines 61-65). Touton '792 does not describe avoiding anaerobic conditions during curing nor does the document address nitrosamine formation in tobacco.

Livingston U.S. Patent 4,836,222

Livingston '222 describes de-greening and coloring tobacco by subjecting the tobacco to air containing ethylene gas as a ripening agent. Livingston '222 discloses that the effects of ethylene are improved by exchanging the air within the curing barn 10-110 times per 24 hour period, which reduces carbon dioxide content and increases oxygen and nitrogen content (column 5, line 43 to column 6, line 55). Livingston '222 does not teach avoiding anaerobic conditions during curing to produce cured tobacco having reduced nitrosamine content.

Moore, Jr. U.S. Patent 2,475,568

Moore, Jr. describes a process for curing bright-leaf tobacco. Moore, Jr. discloses drying yellowed leaves by drawing air from inside a shed housing an oil burner (*see* Fig. 1); heating the air to 100 to 120 or 130 °F; and forcing the heated air into the barn at about 4,000 cubic feet per minute (CFM). Drying the tobacco in this manner is said to increase the rate of drying without damaging the tobacco's cell structure (column 5, lines 15-41). Higher temperatures (above 120 or 130°F) are said to progressively deteriorate cell structure (column 5, lines 51-57). Moore, Jr. does not describe avoiding anaerobic conditions during curing, nor does the document address nitrosamine formation in tobacco.

Wilson U.S. Patent 3,664,034

Wilson '034 discloses a tobacco curing barn having air flow throttling damper members for selectively adjusting air flow during yellowing and drying (column 5, lines 30-32 and column 6, lines 53-71). A fresh air inlet also has a damper member to adjust the amount of air introduced to control relative humidity of the curing air (column 3, line 74 to column 4, line 15). Air flow is increased to 50-120 CFM during the later stages of stem and leaf drying (column 5, lines 22-32). Wilson '034 does not teach avoiding anaerobic conditions during curing. Indeed,

direct-fired heating is illustrated as being the preferred heat source. Wilson does not in any way address nitrosamine formation in tobacco.

Other Documents

The remaining documents listed on the enclosed form PTO-1449 have been considered but are believed to be no more relevant than those discussed above. Bokelman U.S. Patent 4,355,648 and Buensod U.S. Patent 1,568,316 were discussed and fully distinguished during the prosecution of allowed parent application Serial No. 09/397,018.

REMARKS

Applicant respectfully submits that none of the documents describes or suggests the claimed process of substantially preventing the formation of at least one nitrosamine. In the claimed process, uncured tobacco in a susceptible state is dried in a controlled environment which avoids an anaerobic condition in the vicinity of the plant. As described in the specification, *e.g.*, page 10, line 16 to page 11, line 2, the controlled environment can be obtained by selecting an appropriate combination of curing parameters such as airflow, temperature, and humidity. Anaerobic conditions can result, *e.g.*, from the presence of combustion exhaust gases inside the curing barn or from the release of carbon dioxide by the plant during cure. Such anaerobic conditions are believed to contribute to nitrosamine formation by microbial action (specification, page 14, lines 5-17).

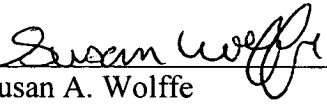
None of the documents describes controlling curing conditions to avoid an anaerobic condition around the vicinity of the plant, so as to substantially prevent the formation of nitrosamines, as in the claimed process.

Indeed, claims broader in scope than pending claims 29-61 have been allowed in parent Application Serial No. 09/397,018. Pending claims 29-61, which are narrower in scope, are allowable for at least the same reasons that the broader claims were allowed in the parent application.

In view of the Petition to Make Special submitted herewith, Applicant respectfully requests prompt review and consideration of the attached documents and this application.

Respectfully submitted,

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